

quickly bring the application to issuance and reserves the right to pursue the cancelled subject matter in this or any related application.

With entry of the above Amendment and in view of the Examiner's interview, Applicant respectfully submits that claims 1-4 and 7-22 are in condition for allowance. Accordingly, reconsideration and withdrawal of the outstanding rejections and allowance of claims 1-4 and 7-22 is respectfully solicited. Applicant respectfully requests early and favorable notification to that effect. Submitted with this Amendment is an Information Disclosure Statement for consideration by the Examiner.

Respectfully submitted,

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**Version with Markings to Show Changes Made to the Claims**

1. (Thrice [Twice] Amended) A stable, aerosolizable composition that is pharmaceutically suitable for rapid bronchial delivery to a lung of a subject, the composition comprising a therapeutically effective amount of delta-9-tetrahydrocannabinol in a pharmaceutically-acceptable semiaqueous solvent comprising volumetric ratios of 10-70 parts of ethanol, 10-30 parts of water and >20-80 parts of propylene glycol having a combined total of 100 [an alcohol, water and a glycol], provided that:

(i) upon aerosolation the composition to a mean mass median aerodynamic diameter in the range from about 1 up to about 10  $\mu$ M; and

(ii) the ratio of the ethanol [alcohol], water and propylene glycol produces a stable clear solution near the solubility point of the delta-9-tetrahydrocannabinol such that upon administration to the lung, the partitioning of the delta-9-tetrahydrocannabinol from the solvent is enhanced so as to reach the bloodstream.

7. (Amended) A composition as defined in Claim 1[6] wherein the volumetric ratios of ethanol : water : propylene glycol are selected from those in the range of from 10 – 70 : 10 :  $\geq$ 20 – 80, respectively, having a combined total of 100.



Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: An After-Final Amendment was filed in this case on February 19, 2002. The Examiner inquired as to incorporate the limitations of claim 6 into claim 1 and to further limit the range of propylene glycol to be greater than 20. The Attorney advised the Examiner that he is currently away from the office and thus unable to approve any amendments to the claims.

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